UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	MDL No. 02419 Docket No. 1:13-md-2419-RWZ
This document relates to:	)	
Handy v. Box Hill Surgery Center, LLC, et al. No: 1:14-cv-14019-RWZ	)	
Armetta v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14022-RWZ	)	
Torbeck v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14023-RWZ	)	
Kashi v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14026-RWZ	)	
Bowman v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14028-RWZ	)	
Dreisch v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14029-RWZ	)	
Davis v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14033-RWZ	)	
Farthing v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14036-RWZ	)	

BOX HILL DEFENDANTS' CONSOLIDATED MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION FOR PARTIAL SUMMARY JUDGMENT CONCERNING THE LEVEL OF "DUE DILIGENCE" PERFORMED PRIOR TO PURCHASING MEDICATIONS FROM NECC

Defendants, Box Hill Surgery Center, L.L.C., Ritu T. Bhambhani, M.D., and Ritu T. Bhambhani, M.D., L.L.C. (hereinafter, collectively "Defendants," "Box Hill Defendants," or "Box Hill"), by undersigned counsel, submit this memorandum of law in support of their Motion For

Summary Judgment, pursuant to Rule 56 of the Federal Rules of Civil Procedure and the authority cited below.

I. INTRODUCTION

In each of the above captioned cases, Plaintiffs asserted claims alleging that the Box Hill Defendants had a "due diligence" duty, breached that duty, and that the breach caused Plaintiffs' injuries. The Box Hill Defendants now move for summary judgment on that issue as a matter of law.

The Court is well-versed on the background of these cases. Accordingly, the Defendants will refrain from restating all of the issues in these cases, which do not otherwise apply to the singular claim addressed in this motion for summary judgment.

In short, thousands of health care providers across the country purchased drugs from the New England Compounding Center ("NECC") even in just the five months preceding the meningitis outbreak at issue.[1] NECC shipped their drugs to health care providers all across the country who administered the drugs to their patients using their own medical judgment. There is no dispute that NECC was the source of contaminated preservative-free methylprednisolone acetate ("MPA") that resulted in the fungal meningitis outbreak. There is no dispute that the Box Hill Defendants ordered preservative-free MPA from NECC and that preservative-free MPA was shipped from NECC to the Box Hill Defendants. Three lots of contaminated preservative-free MPA were recalled by NECC, which included: Lot # 05212012@68 (BUD 11/17/2012); Lot # 06292012@26 (BUD 12/26/2012); and Lot # 08102012@51 (BUD 2/6/2013).[2] The MPA in these

[1] *See* NECC Customer List Since 5/21/2012, excerpts attached as **Exhibit 2**.

[2] The Lot number denotes the date of the lot's manufacture or compounding. The "BUD" is a "Beyond Use Date," which identifies the point after which a drug should no longer be used. A recent indictment of NECC owners and employees described actions whereby NECC owners and employees fraudulently labeled vials of MPA to indicate a later, incorrect BUD or to suggest that the drugs had been properly tested and were not contaminated.

lots was shipped to health care providers, including the Box Hill Defendants, who administered the drugs to patients before it was discovered that the lots were contaminated.

The factual record establishes that NECC represented to potential purchasers that its processes and products fully complied with the recognized standards applicable to compounded medications. As such, the Box Hill Defendants would have learned the same information upon such an inquiry to NECC. Furthermore, thousands of other health care providers, including some of the nation's most prestigious institutions, purchased pharmaceuticals from MPA. *See* Deposition Transcript of Dr. Lloyd R. Saberski, 58:3–58:8, 61:15–62:11, excerpts attached as **Exhibit 10**.

As more fully set forth below, the Box Hill Defendants are entitled to summary judgment as to all claims that relate to any asserted "due diligence" duty because, even if such a duty did exist, any breach thereof did not cause the contamination which resulted in Plaintiffs' injuries.

II. STATEMENT OF FACTS[3]

1. The Plaintiffs' alleged injuries and causes of action arise from the fungal meningitis outbreak caused by contaminated, preservative-free, methylprednisolone acetate ("MPA") manufactured and sold by the New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC").[4]

2. The tainted vials were limited to certain lots: Lot # 05212012@68 (BUD 11/17/2012); Lot # 06292012@26 (BUD 12/26/2012); and Lot # 08102912@51 (BUD 2/6/2013).[5]

[3] The actual exhibits referenced herein are all included with and following the Statement of Undisputed Material Facts.
[4] Dreisch Complaint at 3, ¶ 1.
[5] Dreisch Complaint at 17, ¶ 51.

3. The Plaintiffs' claims against the Box Hill Defendants arise from alleged injuries suffered from potential exposure to MPA administered by Dr. Bhambhani and the Box Hill Defendants while performing epidural steroid injection procedures.[6]

4. Dr. Bhambhani and the Box Hill Defendants purchased preservative-free MPA from NECC because her previous employer used it, she had good results with it, and she was concerned about adverse events caused by preservatives.[7]

5. Similarly, thousands of health care providers across the country purchased drugs from the New England Compounding Center ("NECC") even in just the five months preceding the meningitis outbreak at issue.[8]

6. NECC was regulated and inspected by the U.S. Food and Drug Administration ("FDA").[9] In a letter to Mr. Cadden and NECC dated December 4, 2006, the FDA affirmed its position that "the Federal Food, Drug, and Cosmetic Act ("FDCA") establishe[d] agency jurisdiction over 'new drugs,' including compounded drugs."[10]

7. In addition to such regulatory oversight, NECC also passed the inspection of the Massachusetts Board of Registration in Pharmacy about a year prior to the outbreak, and Brigham and Womens Hospital, a highly accredited and respected healthcare institution, as recently as a week prior to the time that the first batch of recalled MPA solution was manufactured in May 2012.[11]

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[6] Dreisch Complaint at 37, ¶ 145.
[7] *See* Deposition Transcript of Ritu T. Bhambhani, M.D., 71:25–73:16, excerpts attached as **Exhibit 1**.
[8] *See* NECC Customer List Since 5/21/2012, attached as **Exhibit 2**.
[9] *See* FDA Warning Letter, attached as **Exhibit 3**.
[10] *Id*.
[11] *See* Commonwealth of Massachusetts Inspection Report, attached as **Exhibit 4**; Brigham and Women's Hospital Department of Pharmacy USP <797> Audit of NECC, attached as **Exhibit 5**; Brigham and Women's Vendor Audit Survey Form, attached as **Exhibit 6**.

8. After receiving orders from healthcare providers like Dr. Bhambhani, NECC failed to "follow either the proper USP 797 autoclaving sterilization procedure or its own standard operating procedure," failed to take action on at least twenty-six occasions between January 2012 and September 2012 despite results from an internal environmental monitoring program that recorded bacteria and mold in the clean rooms used to produce "sterile" drug products, and distributed two lots of the recalled MPA before receiving results from sterility testing.[12]

9. The parties are in agreement that the applicable standard of care and professional practice did not require the Box Hill Defendants to travel to the NECC facility to perform an inspection prior to purchasing medications from NECC.[13]

10. On March 22, 2017, Barry Cadden, the owner and head pharmacist of NECC, was convicted by a federal jury of racketeering, racketeering conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead in connection with the 2012 nationwide fungal meningitis outbreak.[14] As a result of his criminal conduct, Mr. Cadden was subsequently sentenced to nine years in prison.[15]

11. In the summer and fall of 2012, NECC failed to fulfill its duty to accurately represent the safety and quality of its products to consumer and potential consumers and, in doing so, broke the law.[16]

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[12] Dreisch Complaint at 20, ¶ 66; *Id*. at 22, ¶ 81; *Id*. at 19, ¶ 64.

[13] *See* Deposition Transcript of Dr. Lloyd R. Saberski, 67:7–67:10, excerpts attached as **Exhibit 7**; *see also* Deposition Transcript of Dr. Laxmaiah Manchikanti, 104:10–105:6, excerpts attached as **Exhibit 8**.

[14] *Owner of New England Compounding Center Convicted of Racketeering Leading to Nationwide Fungal Meningitis Outbreak*, U.S. DEPT. OF JUSTICE (Mar. 22, 2017), https://www.justice.gov/usao-ma/pr/owner-new-england-compounding-center-convicted-racketeering-leading-nationwide-fungal.

[15] Pharmacist in meningitis outbreak that kills dozens gets 9 years in prison, BOSTON GLOBE (June 26, 2017), https://www.bostonglobe.com/metro/2017/06/26/feds-cadden-should-pay-for-fungal-meningitis-outbreak/kwet31ZTnsT4lpq4WRzkXO/story.html.

[16] *See* Deposition Transcript of Dr. Lloyd R. Saberski, 65:5–65:18, excerpts attached as **Exhibit 7**.

12. NECC's actions fell below the standard of care with regard to the contaminated lots of MPA.[17]

13. The Box Hill Defendants' procurement of medications from NECC without using patient-specific prescriptions had no effect on whether the medications received were contaminated.[18] Plainly stated, using patient-specific prescriptions would not have prevented Plaintiffs' injuries.[19]

14. The conduct of NECC, rather than the Box Hill Defendants, caused the MPA to be contaminated.[20]

15. NECC's actions were both the actual and proximate cause of the injuries suffered by Plaintiffs.[21]

III. STANDARD OF REVIEW

A moving party is entitled to summary judgment if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(c)(2). The moving party is "entitled to judgment as a matter of law" when it makes a sufficient showing on all essential elements of its case to which it has the burden of proof. *Celotex Corp. v. Catrett*, 477 U.S. 317, 317–18 (1986). If the non-moving party fails to make a sufficient showing on an essential element of his case, on which he would bear the burden of proof at trial, summary judgment is proper. *Id*. at 322.

A nonmoving party may avert summary judgment by showing that there exist specific facts that would present a genuine issue for trial. *Id*. at 324. To establish a genuine issue of fact sufficient

[17] *See* Deposition Transcript of Dr. David Chason, 120:1–121:11, excerpts attached as **Exhibit 9**.
[18] *See* Deposition Transcript of Dr. Lloyd R. Saberski, 167:13–168:16, excerpts attached as **Exhibit 7**.
[19] *See id*.
[20] *See id*., 64:7–65:1, excerpts attached as **Exhibit 7**.
[21] *See* Deposition Transcript of Dr. David Chason, 120:1–121:11, excerpts attached as **Exhibit 9**.

to warrant trial, the nonmoving party "must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). The nonmoving party must set forth "specific facts showing there is a genuine issue for trial." *Anderson*, 477 U.S. at 248 (quoting FED. R. CIV. P. 56(c)(2)).

IV. LEGAL ARGUMENT

Under Maryland law, a plaintiff must allege sufficient facts to meet each element of a medical negligence claim, namely (1) the existence of a duty, (2) a breach of the duty, (3) that the plaintiff suffered actual injury or loss, and (4) that the loss or injury proximately resulted from the defendant's breach of the duty. *See Dehn v. Edgecombe*, 384 Md. 606, 619, 865 A.2d 603, 611 (2005); *Horridge v. Social Services*, 382 Md. 170, 182, 854 A.2d 1232, 1238 (2004); *Patton v. USA Rugby*, 381 Md. 627, 635-36, 851 A.2d 566, 570 (2004).

In Count I of their respective Complaints, Plaintiffs set forth what appears to be a laundry list of "duties" that the Box Hill Defendants allegedly owed to them as a result of the physician-patient relationship. Under the guise of these "duties," it is essentially alleged that the Box Hill Defendants were required to inspect, investigate, and otherwise supervise NECC's compounding procedures, testing and safety policies, and its production facilities. Plaintiffs couch these "duties" as engaging in a "due diligence" of sorts prior to lawfully purchasing preservative-free MPA (hereinafter "MPA") from NECC.

Plaintiffs' claims, however, fail as a matter of law because no such duties exist under Maryland law and certainly did not exist at the time giving rise to the alleged causes of action. Even assuming, *arguendo*, that such a "due diligence" duty did exist, Plaintiffs' claim would also fail on grounds of causation as the undisputed facts are devoid of any support for the contention that any breach of the asserted "due diligence" duty was the cause of NECC's contamination of the MPA. In fact, even Plaintiffs' common-issue experts agree that the Box Hill Defendants did

not cause the contamination. *See* Deposition Transcript of Dr. David Chason, 118:11–118:14, excerpts attached as **Exhibit 11**; *see also* Deposition Transcript of Dr. Lloyd R. Saberski, 64:7–65:1, excerpts attached as **Exhibit 10**. In short, the alleged negligence of the Box Hill Defendants and the contamination of the MPA are too remotely connected to satisfy a causal relationship such that the Box Hill Defendants could be held liable for the injuries allegedly sustained by Plaintiffs. Accordingly, the Box Hill Defendants are entitled to summary judgment as to Plaintiffs' claims that are founded in the contention that the Box Hill Defendants owed the Plaintiffs the duty of "due diligence."

A. The Box Hill Defendants did not have a duty to engage in any type of special "due diligence" prior to lawfully purchasing medication from NECC.

This Court must begin its analysis of this negligence action with the question of whether a legally cognizable duty exits. *See Patton,* 381 Md. at 636, 851 A.2d at 571 (2004); *Remsburg v. Montgomery,* 376 Md. 568, 582, 831 A.2d 18, 26 (2003). A duty, which is known as a standard of care when referring to medical negligence, is defined as what a reasonably prudent physician or health care provider would be required to do under same or similar circumstances in the care and treatment of a patient. *Board of Physicians v. Bernstein,* 894 A.2d 621, 645, 167 Md. App. 714 (2006). The determination as to whether there is a duty is significant because "[t]here can be no negligence where there is no duty that is due." *Patton,* 381 Md. at 636, 851 A.2d at 570 (citing *W. Va. Central R. Co. v. State ex rel. Fuller,* 96 Md. 652, 666, 54 A. 669, 671-72 (1903)).

Maryland courts have applied a "foreseeability of harm" test, "which is based upon the recognition that duty must be limited to avoid liability for *unreasonably remote consequences*." *Doe v. Pharmacia & Upjohn Co.*, 388 Md. 407, 879 A.2d 1088, 1092-93 (2005) (emphasis added) (quoting *Coates v. Southern Md. Electric,* 354 Md. 499, 509 (1999). The existence of a duty in a

negligence action is a question of law to be decided by the court. *Dehn*, 384 Md. at 619-20, 865 A.2d at 611; *see also Patton*, 381 Md. at 636, 851 A.2d at 570.

There is no authority supporting the "due diligence" duty proffered by Plaintiffs. Maryland law does not impose a duty on physicians or medical clinics to regulate the pharmacies from which they lawfully purchase medications, nor does Maryland law impose a duty on physicians to visit and/or evaluate a licensed pharmacy's compounding facility prior to purchasing medications as Plaintiffs have shockingly alleged. Plaintiffs not only fail to provide support for such an imposition, but they also fail to cite to any case law that held or found such a duty because no such case law or support exists. In this instance, it is clear that it was the duty of the Massachusetts Board of Pharmacy,[22] the Maryland Board of Pharmacy, or the FDA, not Dr. Bhambhani, a single Maryland physician, to regulate and license NECC and to ensure that NECC complied with applicable pharmacy laws, established by those entities.

The only duty imposed on the Box Hill Defendants was that they exercise reasonable care in their underlying care and treatment of the patients involved in these actions. This duty is and was premised on what other reasonable and similarly situated individuals and clinics in the medical community did, and how they acted, at the time that the care occurred—not traveling around the country to every manufacturer for every product that might lend itself to a dangerous situation, in order to oversee, inspect and ensure compliance. Pharmaceutical medications are by their very nature often "unavoidably unsafe products" with a known but apparently reasonable risk. *See* Restatement (Second) of Torts § 402A, comment k (1965). Would it make sense that a physician would have to inspect the facility that manufactures Tylenol because adverse reactions might develop? Combined with the fact that state and federal licensing agencies and regulators are also

[22] The Massachusetts Board of Pharmacy is also known as the "Massachusetts Board of Registration in Pharmacy."

required to regulate, license, and oversee manufacturers, like the Massachusetts Board of Pharmacy and the FDA to NECC, Plaintiffs' suggestion that the Box Hill Defendants also had that duty would be insincere at best and ludicrous at worst and is not established.

Dr. Bhambhani and the Box Hill Defendants were well within their legal right to purchase medication from a licensed pharmacy that had licensed pharmacists and from whom thousands of other similarly situated physicians and clinics purchased medications and products, without ensuring that particular pharmacy complied with Massachusetts law. To further elucidate this point, the Box Hill Defendants also purchase syringes, sterile dressings, sedatives, and other drugs and products that could potentially lead to serious injury, infection, and/or death if not handled appropriately by a manufacturer. Health care providers in a similar position to the Box Hill Defendants are not required under those circumstances, either, to first launch an investigation against each separate manufacturer and to make annual, unannounced visits to dozens of manufacturing facilities across the country throughout the year before they can purchase those other potentially dangerous products. Plaintiffs have not countered that fact with any evidence in this litigation.

Further, Maryland law does not impose a duty on physicians and/or clinics, nor does it require them, to purchase medications from an FDA-regulated drug manufacturer as Plaintiffs suggest. Nevertheless, NECC had been monitored and regulated by the FDA, and the FDA maintained their right to regulate NECC. *See* FDA Warning Letter, attached as **Exhibit 12**. Again, Plaintiffs' Complaints do not offer anything other than bald assertions and legal conclusions couched as facts to support those claims. Accordingly, the Box Hill Defendants were fully permitted to purchase MPA from a compounding pharmacy, such as NECC, and doing so did not breach any duty owed to Plaintiffs.

Consistent with the practices of her reasonable peers, Dr. Bhambhani and other physicians (and the Box Hill Defendants) do not have a duty to regulate pharmacies or to engage in any type of special due diligence inspection or investigation prior to lawfully purchasing medications from a licensed pharmacy, such as NECC. Maryland law has never recognized any such duties with respect to physicians and/or clinics and the imposition of the same would mark a drastic expansion of existing law, and one better left to the legislature and policy makers, not the courts.

As a result of Plaintiffs' inability to establish a legally cognizable "due diligence" duty, Plaintiffs' claim necessarily fails and the Box Hill Defendants are entitled to judgment as a matter of law.

B. The level of "due diligence" performed by the Box Hill Defendants prior to purchasing medication from NECC does not bear a causal relationship with Plaintiffs' alleged harms.

Causation is an essential element of a negligence claim. For a plaintiff to recover damages, a defendant's negligence must be a cause of a plaintiff's injuries. *Supra*. The causation element consists of factual and proximate cause. Factual cause is the "but for" aspect of causation. A negligent act is only deemed the factual cause of an outcome if, in the absence of the act, the outcome would have been avoided. *See Peterson v. Underwood*, 258 Md. 9, 16, 264 A.2d 851 (1970). If there is no causation in fact, then no further analysis is necessary because the causation element is insufficient. *Mackin v. Harris*, 342 Md. 1, 8, 672 A.2d 1110 (1996). If there is causation in fact, the inquiry continues to proximate cause.

Proximate cause ultimately involves a conclusion that someone will be held legally responsible for the consequences of an act or omission. This determination is subject to considerations of fairness or social policy as well as mere causation. *See Yonce v. Smithkline Beecham Clinical Lab*, 111 Md. App. 124, 680 A.2d 569 (1996). Negligent acts (such as a breach

of a standard of care) are not actionable unless the injury is the natural and probable result or consequence of the negligent act or omission. *Medina v. Meilhammer*, 62 Md. App. 239, 489 A.2d 35 *cert. denied*, 303 Md. 683, 496 A.2d 683 (1985). Often proximate cause is not proven because the negligent act was too far removed from the harm or the nature or extent of the harm was unforeseen. *See Peterson*, 258 Md. at 18–20. Further, the actor's conduct may be held not to be a legal cause of harm where after the event, looking back from the harm to the actor's negligent conduct, it appears to the court highly extraordinary that it should have brought about the harm. *Hartford Ins. Co. v. Manor Inn*, 335 Md. 135, 157 n. 6, 642 A.2d 219. (1994). Moreover, an intervening cause, whether superseding or responsible, can break the chain of proximate causation if the negligence would have occurred even without the initial actor's alleged negligence. *See Yonce, supra.* As suggested, this is a determination made by the Court if the facts of the underlying actions are not disputed, *Lashley v. Dawson*, 162 Md. 549, 563, 160 A. 738 (1932), as is the case here.

Plaintiffs' assertion that the Box Hill Defendants were negligent in procuring medication from NECC fails as a matter of law because, even assuming *arguendo* that such a duty exists, the level of "due diligence" performed does not bear a causal relationship with the Plaintiffs' alleged harms. Plaintiffs were harmed by contaminated MPA, which resulted from NECC's failure to properly manufacture and utilize appropriate sterility practices while compounding MPA. The actions taken by the Box Hill Defendants simply had nothing to do with the actual cause, or cause-in-fact, of the contamination, and the alleged acts of negligence by the Box Hill Defendants are too remotely connected. Further, the intervening (and fraudulent) acts of NECC are too unforeseeable to satisfy a causal connection between the alleged negligence of the Box Hill Defendants and the injuries allegedly sustained by these patients.

The undisputed facts establish that even if the Box Hill Defendants had completed all the various proposed elements of "due diligence" that the PSC's professional witnesses claim were required, the Box Hill Defendants, acting reasonably and in accordance with a standard of care identical to thousands of others, would have purchased medications from NECC, just like they had done for years without incident, and that the resulting fungal meningitis outbreak would not have been averted. Moreover, the level of "due diligence" the Box Hill Defendants completed prior to purchasing medication from NECC did not cause, or have any remote causal relationship with, an outcome which would not have otherwise occurred.

V. CONCLUSION

For the foregoing reasons, the Box Hill Defendants respectfully request that the Court grant its motion for summary judgment on this issue.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 18th day of September 2017, I served the above Memorandum upon the Clerk of the Court, using the CM/ECF system, which then sent a notification of such filing (NEF) to all counsel of record.

/s/ Gregory K. Kirby
Gregory K. Kirby, Esq.